UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

AMY ARNOLD,

Plaintiff,

v.

Case No. 2:22-cv-1951
Judge Edmund A. Sargus, Jr.
Magistrate Judge Elizabeth P. Deavers

COOPERSURGICAL, INC., *et al.*,

Defendants.

OPINION AND ORDER

This matter is before the Court on Motions for Summary Judgment filed by Plaintiff Amy Arnold (Arnold Mot., ECF No. 109), Defendant Femcare, Ltd. (Femcare Mot., ECF No. 114), Defendant CooperSurgical, Inc. (CooperSurgical Mot., ECF No. 115), and Defendant Utah Medical Products, Inc. ("UTMP") (UTMP Mot., ECF No. 116). This Court dismissed Ms. Arnold's design defect and manufacturing defect claims under Ohio law because they were preempted by federal law. *Arnold v. CooperSurgical, Inc.*, 681 F. Supp. 3d 803, 833 (S.D. Ohio 2023). The Court allowed Ms. Arnold's failure-to-warn claim to continue, holding that it was sufficiently pled.

Now, after Ms. Arnold had the chance to develop her claim through discovery and to defend it against Defendants' motions for summary judgment, the Court determines that Ms. Arnold's failure-to-warn claim is also preempted by federal law. Accordingly, the Court **GRANTS** CooperSurgical's Motion for Summary Judgment (ECF No. 115), **GRANTS** UTMP's Motion for Summary Judgment (ECF No. 116), and **DENIES** Ms. Arnold's Motion for Summary Judgment (ECF No. 109). Because the Court previously dismissed Femcare as a defendant for a lack of personal jurisdiction, the Court **DENIES AS MOOT** Femcare's Motion for Summary Judgment.

(ECF No. 114.) Because the resolution of the motions for summary judgment do not depend on the disputed experts that were the subject of the Parties' various *Daubert* motions, those motions are **DENIED AS MOOT**. (ECF Nos. 110, 111, 112, 117, 118, 119, 120.)

BACKGROUND

I. Factual History

This products liability suit arises from injuries Ms. Arnold sustained in connection with the use of Filshie Clips, a medical device used in tubal ligations. (Am. Compl., ECF No. 40, ¶ 17.) Ms. Arnold brought the action against Defendants CooperSurgical, Inc., The Cooper Companies ("TCC"), Inc., Femcare, Ltd., and UTMP as the companies or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, or sold the Filshie Clip that was surgically implanted in Plaintiff. (*Id.*, PageID 462.) The Court draws on the factual summary previously issued as part of its opinion and order on Defendants' motions to dismiss, supplemented by new evidence provided by the Parties. *See Arnold*, 681 F. Supp. 3d at 810–12.

A. The Filshie Clip and Federal Oversight

The Filshie Clip, created by Marcus Filshie in the late 1970s, is a component of the "Filshie Clip System" for laparoscopic tubal ligation, which involves applying a titanium clip with silicone rubber lining around each fallopian tube. (ECF No. 114-7, ¶ 3; ECF No. 114-3, PageID 2864.) In short, the clip exerts continuous pressure on the fallopian tube, prompting necrosis and decreasing the tube's size, eventually leading to fibrosis. (ECF No. 114-3, PageID 2864.) The Filshie Clip is designed to remain permanently attached to the fallopian tube at its placement location, thus providing a long-term form of birth control. (*Id.*)

The Filshie Clip, like all medical devices sold in the United States, is regulated by the Food

and Drug Administration ("FDA"), which draws its regulatory authority in this area from the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 360c, *et seq*. Class III devices, the class to which the Filshie Clip belongs, are subject to the most extensive federal oversight. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). Before a Class III device can enter the U.S. marketplace, it must undergo a rigorous "premarket approval" ("PMA") process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The FDA grants PMA "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel* at 318 (quoting 21 U.S.C. § 360e(d)). In deciding whether to grant PMA, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C).

If the FDA's review process leads to a device's PMA, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel* at 319 (citing § 360e(d)(6)(A)(i)). Should a manufacturer wish to make such a modification, it must follow the FDA's process for supplemental premarket approval, an evaluation process that largely mirrors that of the initial application. *Id.* Following PMA, "the devices are subject to reporting requirements," including the obligation "to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Id.* (citing 21 C.F.R. § 803.50(a)).

In 1996, the FDA granted PMA for the use of Filshie Clips for female contraception and approved the warnings and precautions included in the device's "Instructions for Use" ("IFU"). (ECF No. 114-4 (FDA device approval); ECF No. 114-5 (FDA IFU approval); Am. Compl., ¶¶ 25–26 (Ms. Arnold acknowledging approval).) The FDA-approved IFU included warnings that three

instances of clip "expulsion per urethra, vaginal cuff and bowel" and two "foreign body reactions" were reported out of 5,454 women treated with the clips. (ECF No. 114-5, PageID 2959.) The IFU also reported that these "instances of apparently asymptomatic migration of the clip" were "incidental," and "the frequency of this event is not known." (*Id.*) Finally, the IFU disclosed "adverse effects" including a 0.13% frequency of "clip migration or expulsion" and a 35.7% frequency of "pain and cramping." (*Id.*, PageID 2960.)

In an article published in 2002, the inventor of the Filshie Clip, G. Marcus Filshie, stated, "It is estimated that over 25% of patients will experience a migration of one or more Clips." (ECF No. 114-6, PageID 3000.) Most of these displaced clips stay inside the body, but some are expelled from the body. (*Id.*) To support this estimate, Dr. Filshie cited a 1999 study on clip migration. (*See id.*, PageID 3000–01.) Femcare reported Dr. Filshie's article to the FDA in its 2007 annual report. (ECF No. 114-2, ¶¶ 4–5; ECF No. 114-8, PageID 3023.) In a sworn declaration, Dr. Filshie states that the 25% estimated migration frequency "was, at best, a guesstimate" possibly based on "limited anecdotal experience" or "informal discussions with colleagues." (ECF No. 114-7, ¶ 10.)

In 2021, the FDA approved an updated Filshie Clip IFU that included two relevant changes. First, the 2021 IFU discloses the same 0.13% clip migration or expulsion rate, but it now describes this type of adverse effect as "symptomatic Clip migration or expulsion." (ECF No. 114-11, PageID 3041 (UTMP and Femcare document describing IFU changes); ECF No. 114-10 (FDA approval of changes).) Second, the IFU now includes a section stating, "Asymptomatic clip migration occurs, but its actual rate is unknown." (ECF No. 114-11, PageID 3041.) It is undisputed that the FDA has never suspended or withdrawn the PMA for the Filshie Clip. (ECF No. 114-2, PageID 2852–53.) It is also undisputed that the FDA has never requested or required disclosure of a 25% clip migration rate to be included in the Filshie Clip IFU. (ECF No. 127, PageID 4271.)

B. Plaintiff's Surgery and Complaint

In early 2003, Ms. Arnold underwent a tubal ligation procedure using Filshie Clips. (ECF No. 114-12, ¶ 5.) In July 2020, Ms. Arnold saw a doctor about vaginal bleeding and pain in her lower pelvic area. (ECF No. 109-4, PageID 2057.) She "underwent a hysteroscopy, [dilation and curettage] and polypectomy . . . for postmenopausal bleeding, thickened endometrium and pelvic pain" in October 2020. (*Id.* PageID 2058.) In January 2022, after a fall on the ice, Ms. Arnold underwent an X-ray of her pelvis and left hip. (*Id.*) The X-ray showed "a tubal ligation clip free in mid left abdomen" that "had been noted on a prior CT." (*Id.*) On a follow up call in February 2022, she "noted migratory abdominal pain for a year or so." (*Id.*) At a doctor's visit in April 2022, she "noted an uncomfortable feeling since her [bilateral tube ligation] in 2003" and that "[s]he has had random pain since then." (*Id.* PageID 2058–59.)

Ms. Arnold claims that Defendants neither warned nor adequately informed her or her healthcare providers how frequently these migrations occur or the attendant injuries that may accompany such migration. (Am. Compl., ¶ 45.) Defendants' actions allegedly breached their duty of reasonable care in the development and promotion of Filshie Clips and their duties as manufacturers and distributors of medical devices to continually monitor and test their product, thus subjecting Defendants to liability under the FDCA and Ohio product liability law. (*Id.* ¶¶ 52–54.)

Plaintiff asserts that, had Defendants complied with FDA regulations and Ohio product liability law, Plaintiff's injuries could have been avoided. (*Id.* ¶ 54.) Plaintiff therefore brought the following state-law claims: (1) strict products liability for design defect, (2) strict products liability for manufacturing defect, and (3) strict products liability for failure to warn. (*Id.* ¶¶ 2, 77–111.)

II. Procedural History

Defendants moved to dismiss on grounds of personal jurisdiction and failure to state a claim upon which relief can be granted. (ECF Nos. 43, 44, 45, 59.) The Court granted TCC's motion to dismiss for a lack of personal jurisdiction. *Arnold*, 681 F. Supp. 3d at 832. Additionally, the Court held that Ms. Arnold's design defect claim was impliedly preempted by federal law under 21 U.S.C. § 337(a) and the U.S. Supreme Court's holding in *Buckman v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001). *Arnold* at 828–29. The Court also held that Ms. Arnold's manufacturing defect claim was expressly preempted under 21 U.S.C. § 360k(a) and that, to the extent the claim was disguised as a "fraud on the FDA" claim, it was impliedly preempted under § 337(a) and *Buckman*. *Arnold* at 830. Accordingly, the Court dismissed with prejudice Ms. Arnold's design defect and manufacturing defect claims against all Defendants. But the Court denied Defendants' motion to dismiss Ms. Arnold's failure-to-warn claim on preemption grounds, finding that the Amended Complaint carefully avoided "alleging that Defendants failed to provide warnings 'beyond' those required by the FDA." *Arnold*, 681 F. Supp. 3d at 831–32.

In a later decision, the Court dismissed Femcare as a defendant for lack of personal jurisdiction. *Arnold v. CooperSurgical, Inc.*, No. 2:22-cv-1951, 2024 WL 4040370, at *8 (S.D. Ohio Aug. 27, 2024). Now, only Ms. Arnold's failure-to-warn claim remains against the last two defendants, CooperSurgical and UTMP.

Before the Court dismissed Femcare as a Defendant, Femcare filed a Motion for Summary Judgment. (Femcare Mot.) CooperSurgical also filed a Motion for Summary Judgment, in which it "join[ed] in the summary judgment motion filed by Defendant Femcare, Ltd. on the basis of federal preemption." (CooperSurgical Mot., PageID 3192.) UTMP also filed a Motion for Summary Judgment and joined in Femcare's motion on the same grounds. (UTMP Mot., PageID

3295.) CooperSurgical and UTMP did not recite Femcare's preemption arguments at length in their own motions. Thus, even though Femcare is now dismissed as a defendant, rendering its motion for summary judgment moot, the Court considers the arguments stated in Femcare's motion and reply as asserted by Coopersurgical and UTMP in the interests of justice and efficiency. Therefore, the Court will refer to arguments raised by Femcare and joined by CooperSurgical and UTMP as arguments advanced by "Defendants" generally.

Ms. Arnold filed a Motion for Summary Judgment on Defendants' Affirmative Defenses. (Arnold Mot.) Regarding preemption, Ms. Arnold merely refers to the Parties' briefing on the issue at the dismissal stage and states that discovery did not yield any new information. (*Id.* p. 5–6.) Defendants filed a combined response in opposition to Ms. Arnold's Motion. (ECF No. 130.) And Ms. Arnold replied. (ECF No. 138.) Separately, Ms. Arnold filed responses in opposition to Defendants' various motions for summary judgment. (ECF Nos. 127, 128, 129.) Defendants followed with replies from Femcare (ECF No. 143), CooperSurgical (ECF No. 144), and UTMP (ECF No. 145).

The Parties also filed *Daubert* motions to exclude or limit the testimony of certain expert witnesses. Ms. Arnold moved to exclude the testimony of Dr. Janesh Gupta (ECF No. 110) and Dr. Howard Sharp (ECF No. 111) and to exclude or limit the testimony of Steven Silverman (ECF No. 112). Defendants moved to exclude the opinions of Dr. Lisa Harris (ECF No. 117), Dr. Bruce Rosenzweig (ECF No. 118), Dr. Joshua Sharlin (ECF No. 119), and Dr. James Wheeler (ECF No. 120).

LEGAL STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

The Court may therefore grant a motion for summary judgment if the nonmoving party who has the burden of proof at trial fails to make a showing sufficient to establish the existence of an element that is essential to that party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see Barnhart v. Pickrel, Schaeffer & Ebeling Co.*, 12 F.3d 1382, 1388–89 (6th Cir. 1993). To avoid summary judgment, the nonmovant "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "[S]ummary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The Parties cross-moved for summary judgment. Each party, as a movant, bears the burden of meeting the summary judgment standard. *Ray v. McCloud*, 507 F. Supp. 3d 925, 930 (S.D. Ohio 2020) (Watson, J.). The failure of one party to carry its burden does not mean that the other party should prevail on its motion; rather, the Court should "evaluate each motion on its own merits and view all facts and inferences in the light most favorable to the nonmoving party." *Wiley v. United States*, 20 F.3d 222, 224 (6th Cir. 1994).

ANALYSIS

This Court previously held that Ms. Arnold's failure-to-warn claim could continue past Defendants' motions to dismiss even though the "precise contours of [Ms. Arnold's] theory of recovery [were], admittedly, not well defined," because such details were not required at the pleading stage. *Arnold*, 681 F. Supp. 3d at 832 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). But now, after the close of discovery and on the Parties' motions for summary judgment, Ms. Arnold must show more. Upon Defendants' showing that Ms. Arnold lacks evidence to support her claim, Ms. Arnold must present evidence on which a jury could reasonably

find in her favor. *See Anderson*, 477 U.S. at 252.

The threshold issue on the Parties' motions for summary judgment is whether Ms. Arnold's state law failure-to-warn claim under Ohio Revised Code § 2307.76 is preempted by federal law. Ohio law provides a failure-to-warn cause of action both for inadequate warnings at the time of marketing and for failure to provide reasonable post-marketing warnings after the medical device leaves the manufacturer's control.

> (A) . . . a product is defective due to inadequate warning or instruction if either of the following applies:
>
> > (1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:
> >
> > > (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
> > >
> > > (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.
> >
> > (2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:
> >
> > > (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
> > >
> > > (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A).

I. Ms. Arnold's Theories of Liability

Ms. Arnold advances multiple theories of recovery under her Ohio Revised Code § 2307.76 failure-to-warn claim regarding Filshie Clips. For the Court's preemption analysis, these theories are organized into two basic categories.

In the first category, Ms. Arnold argues that Defendants failed to warn Ms. Arnold and her health care providers about the potential for migration of the clips. (Am. Compl., ¶ 105; ECF No. 127, PageID 4264–65.) Ms. Arnold claims that the FDA-approved warnings issued pursuant to the Filshie Clip Instructions for Use ("IFU") were inadequate and that the clips "were defective and unreasonably dangerous at the time of their release into the stream of commerce due to the inadequate warnings." (Am. Compl., ¶ 107.) She also argues that Defendants had a duty to warn "under the FDCA and parallel Ohio product liability laws" that continued after Ms. Arnold's surgery and that Defendants failed to issue adequate warnings. (*Id.* ¶¶ 104–05.) In a response brief, Ms. Arnold restates these allegations from her Complaint as the basis for her failure-to-warn claim. (ECF No. 127, PageID 4264–65.)

Ms. Arnold's second category of arguments relates to *why* those warnings might be inadequate. She claims that Defendants had a duty to warn about the risks of harm associated with Filshie Clips that "parallels the FDCA's requirement for truthfully and completely reporting incidents of adverse events, and if necessary, obtaining approval for changes in the design, manufacture, and warnings/marking approved by the FDA." (Am. Comp., ¶ 103.) Ms. Arnold alleges that Defendants failed to report adverse events about Filshie Clip migration to the FDA, violating federal regulations. (*See* Am. Compl., ¶ 103; ECF No. 127, PageID 4265.) She also claims that Defendants failed to report adverse events directly to Ms. Arnold and to her health care

providers. (Am. Compl., ¶ 105; ECF No. 127, PageID 4265.)

Defendants contend that all Ms. Arnold's potential theories of recovery are preempted by federal law. The Court agrees.

A. Federal Preemption Under the FDCA and MDA

Pursuant to the Supremacy Clause of the United States Constitution, "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516, (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)); *see* U.S. Const., art. VI, cl. 2. Defendants argue that Ms. Arnold's state-law failure-to-warn claim is preempted under FDCA as amended by the MDA. (Femcare Mot., PageID 2831 (joined by CooperSurgical Mot., PageID 3192, and UTMP Mot., PageID 3295).)

i. Express Preemption

The MDA preempts state-law claims in two ways. First, the MDA includes a preemption provision expressly preempting certain state law requirements governing medical devices:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is *different from, or in addition to*, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). Thus, "[s]tate requirements are pre-empted under the [MDA] only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting § 360k(a)(1)). The MDA does not, however, expressly preempt state law "claims premised on a violation of FDA regulations" when "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.*

ii. Implied Preemption

Second, claims not expressly preempted under 21 U.S.C. § 360k(a) may still be impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court held that, because the federal government is the exclusive enforcing body of the FDCA, there is no private right of action under the FDCA. *Id.* at 349 n.4. Thus, a private litigant cannot sue a defendant for violating the FDCA. *Id.* at 352–53 ("[W]e have clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government.").

Accordingly, state-law claims by a private litigant that defendants committed a fraud on the FDA by failing to disclose sufficient information to the FDA "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Therefore, state law fraud-on-the-FDA claims where the plaintiff relies on the defendant's failure to comply with FDCA requirements as "a critical element in their case" are impliedly preempted under federal law. *Id.* at 353; *see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 936 (6th Cir. 2014) (holding negligence claims preempted under *Buckman* where "the conduct that [p]laintiffs allege gives rise to their statutory negligence claims is the [defendants'] violation of the FDCA.").

B. Failure to Follow FDA Labeling Requirements

As established above, it is undisputed Defendants obtained FDA approval to sell and market Filshie Clips in 1996 and that the FDA's approval has never been suspended or withdrawn. It is also undisputed that the FDA approved the Filshie Clip IFU in 1996 and that the FDA-approved IFU in force at the time of Ms. Arnold's surgery included the same warnings. (ECF No. 114-2, ¶ 10; ECF No. 114-5, PageID 2955–73.) Ms. Arnold's assertions that Defendants' warnings were inadequate relate both to Defendants' obligations to issue warnings before Ms. Arnold's

surgery and after the surgery, *i.e.*, after the device left the Defendants' control. The Court examines both arguments through a preemption lens.

i. Adequacy of Warnings at the Time of Surgery

The Parties agree that FDA regulations applied to Filshie Clips at the time of Ms. Arnold's surgery. Thus, any state law warning requirements for Filshie Clips are expressly preempted to the extent those requirements are "different from, or in addition to" the FDA regulations. 21 U.S.C. § 360k(a). It is undisputed that the FDA has never requested or required disclosure of a 25% migration rate in the Filshie Clip's IFU. (*See* ECF No. 127, PageID 4271.) Nonetheless, Ms. Arnold argues that the warnings themselves were inadequate regarding the risks of migration and expulsion because they did not disclose a 25% migration rate, even though the warnings were FDA-approved. (*See* Am. Compl., ¶¶ 105, 107; ECF No. 127, PageID 4264–65 (restating arguments from Am. Compl.).) Thus, by arguing under Ohio law that the warnings applicable at the time of her surgery were inadequate, Ms. Arnold, by necessary implication, argues that Defendants should have given warnings beyond what was required by the FDA.

This type of argument is expressly preempted under federal law because any additional requirements "would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA and supplement process." *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) (quoting 21 U.S.C. § 360k(a)); *see Kemp v. Medtronic*, 231 F.3d 216, 236 (6th Cir. 2000) ("[T]o the extent that plaintiffs' claim is premised on the adequacy of the warnings reviewed and approved by the FDA . . . the claim is . . . preempted.") Thus, to the extent Ms. Arnold's failure-to-warn claim is premised on the failure to give warnings beyond what the FDA required at the time of her surgery, her claim is expressly preempted under federal law.

ii. Adequacy of Warnings After Marketing and Surgery

Ms. Arnold's next theoretical basis for liability relates to Defendants' ongoing alleged failure to include adequate warnings in the IFU about the risks of harm from Filshie Clips after they left Defendants' control and after Ms. Arnold's surgery. (Am. Compl., ¶¶ 104–05.) Her theory of reliability depends on a discussion of failure-to-warn claims in dicta in *Kemp*. There, the Sixth Circuit suggested that a failure-to-warn claim under Ohio Revised Code § 2307.76 could lie where the plaintiff asserts "that [the] defendant acquired information subsequent to the FDA approval . . . that would lead a reasonable manufacturer to warn patients and the medical community." *Kemp*, 231 F.3d at 236–37. Even so, the court in *Kemp* was not presented with such a post-approval claim, and thus it did not weigh the preemption effects of the FDA's post-PMA supplemental reporting and approval process on such claims. *Id.* Ms. Arnold argues she has raised the permissible claim contemplated in *Kemp*, but undisputed evidence regarding Defendants' compliance with post-PMA FDA warning requirements makes clear that her claim is preempted.

In *Cupek*, the Court addressed a "post-sale," failure-to-warn claim where the plaintiff asserted that the defendant had an independent state law duty to issue warnings due to "information learned after FDA review" of supplemental FDA filings. 405 F.3d at 422–23. The Sixth Circuit observed that "the FDA requires continuous updates as part of the [PMA] application and supplement process" as part of its process for deciding whether to require new warnings after a PMA is issued. *Id.* at 424 (citing *Kemp*, 231 F.3d at 221–22; 21 U.S.C. §§ 360h(a), 360e(1) and (2)(a); 21 C.F.R. §§ 803.50 (requiring device manufacturers to report adverse medical device events to the FDA), 810.10); *see also* 21 U.S.C. § 360i (requiring device manufacturers to report serious injury incidents to the Secretary of Health and Human Services)).

Accordingly, the Sixth Circuit held that federal law expressly preempted plaintiffs' post-

sale failure-to-warn claim because any independent state law requirements to issue warnings *beyond* those required by the FDA "would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process." *Cupek*, 405 F.3d at 424. In other words, any independent state law requirements to issue "post-sale" warnings beyond what is required by the FDA are preempted because they would not "parallel" federal law. *Id.* (citing *Buckman*, 531 U.S. at 353).

Here, this Court denied Defendants' motions to dismiss Ms. Arnold's failure-to-warn claim because Ms. Arnold had sufficiently cabined her state law allegations to those that parallel, rather than add to, federal law requirements. *Arnold*, 681 F. Supp. 3d at 832 (citing *Kemp*, 231 F.3d at 236–37.) But now, based on the evidence and briefing presented at the summary judgment stage, Ms. Arnold argues that Defendants' ongoing, post-marketing and post-surgery warnings were inadequate, even though the FDA had an ongoing, post-PMA reporting process with which Defendants were required to comply. (*See* ECF No. 127, PageID 4272 (Ms. Arnold argues that "Defendants did not 'adequately warn[]' any learned intermediaries (medical professionals via FDA approved communications) the true risk of migration.").) Accordingly, Ms. Arnold's claim is not the potentially viable failure-to-warn claim discussed in *Kemp*.

It is undisputed that the Filshie Clips were subject to FDA surveillance and reporting requirements after the FDA issued the PMA in 1996 and that the post-PMA requirements continued up through and after Ms. Arnold's surgery in 2003. (ECF No. 127, PageID 4265.) As explained above, Defendants provided evidence that they submitted supplemental information to the FDA under those FDA requirements. (*See supra*, Background Part I.A.) Ms. Arnold does not refute the evidence presented by Defendants that Defendants complied with the FDA's ongoing IFU warning requirements after her surgery. (ECF No. 114-2, ¶¶ 3, 9.) In fact, she acknowledges

that the FDA has *never* required the warning she says should have been given—that the Filshie Clips have a potential 25% migration rate. (ECF No. 127, PageID 4271.)

Instead, Ms. Arnold asserts that Defendants breached a parallel state law duty under Ohio Revised Code § 2307.76 to issue warnings in the IFU about Filshie Clip migration risks. But her argument is necessarily premised on an assertion that Defendants *complied* with federal warning requirements and *even so* are liable under state tort law. Therefore, the state law duty she asserts exists is not merely "parallel" to federal requirements. Indeed, such a duty necessarily would be "different from" or "in addition to" the FDA's post-surgery warning requirements issued in accordance with its post-PMA reporting and approval process. Under *Cupek*, such arguments regarding independent "post-sale" duties to issue IFU warnings under state law are expressly preempted by 21 U.S.C. § 360k(a). *See Cupek*, 405 F.3d at 424.

C. Failure to Report Adverse Events

Facing these express preemption barriers to her state law failure-to-warn claim, Ms. Arnold raises an alternative theory of liability at summary judgment. Since the dismissal stage, Ms. Arnold has more clearly articulated that her failure-to-warn theory of liability expressly relies on Defendants' alleged failure to report adverse events to the FDA, the medical community, and Ms. Arnold. (ECF No. 127, PageID 4265, 4269 ("Because the Defendants failed to report adverse events, the FDA would not have known about the types of injuries these women experience, and thus would not be able to approve of an accurate warning.").) With those more "precise contours" of her theory now defined, her failure-to-warn claim is fully preempted by federal law.

To start, the Court has rejected this theory of liability in the design defect context. In the decision on Defendants' motions to dismiss, the Court held that Ms. Arnold's design defect claim was impliedly preempted because "'permitting a fraud claim premised on false representations to

the FDA during the PMA process would conflict with well-established precedent that no implied private right of action exists under the FDCA.'" *Arnold*, 681 F. Supp. 3d at 828 (quoting *Kemp*, 231 F.3d at 236). Furthermore, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman Co.*, 531 U.S. at 350; *see also Marsh v. Genentech, Inc.*, 693 F.3d 546, 553–54 (6th Cir. 2012) ("Having a court determine whether any non-disclosed information may reasonably affect the statement of contraindications, warnings, precautions or adverse reactions in the draft labeling . . . would both usurp the agency's role and go beyond the court's institutional expertise." (internal quotations and citations omitted)). Accordingly, such claims are impliedly preempted under the FDCA, as amended by the MDA. *Id.* at 344.

In addition to the reasons cited above, Ms. Arnold's failure-to-warn claim regarding Defendants' failure to report adverse events to the FDA is preempted because she does not identify a parallel duty under state law to report adverse events to the FDA. (*See* ECF No. 127.) As this Court has observed, "[t]here is, conversely, no state-law requirement that medical-device manufacturers submit adverse-event reports to the FDA." *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1006 (S.D. Ohio 2016) (Black, J.). In the evidence and briefing submitted at this stage, Ms. Arnold does not identify a state law source of such a reporting obligation predating the FDA's reporting requirements. Thus, in her failure-to-warn claim, in essence, she asserts that Defendants should be liable merely *because* they violated the ongoing adverse event reporting requirements of the FDCA, as amended by the MDA. Such a claim is impliedly preempted. *Buckman*, 531 U.S. at 347–48; *see Farson v. Coopersurgical, Inc.*, No. 3:22 CV 716, 2023 WL 5002818, at *11 (N.D. Ohio Aug. 4, 2023) (Knepp II, J.) ("[W]hen reliance on a failure to report adverse events 'is a critical element in [a plaintiff's] case, [the plaintiff] would not be relying on traditional state tort

law,' even if the plaintiff states that is what she is doing." (quoting *Buckman*, 531 U.S. at 353)).

Furthermore, Ms. Arnold's argument that Defendants are liable for failing to warn Ms. Arnold and her physicians about adverse events is also preempted by federal law. To be clear, "[a]dverse-event reports are not warnings." *Aaron*, 209 F. Supp. 3d at 1005 ("Doctors are warned of the risks associated with a medical device *through the device's labeling*, not through adverse-event reports submitted to the FDA."). Thus, as this Court has held, "the federal duty to report certain information to the FDA is not 'identical,' . . . and thus not parallel, to the state-law duty to provide warnings to patients or their physicians." *Id.* (citing *Lohr*, 518 U.S. at 495). Furthermore, "because the FDCA does not require that a manufacturer furnish adverse-event reports directly to physicians, any state-law requirement that a manufacturer do so is different from, or in addition to, any requirement applicable under the FDCA and its implementing regulations, and is pre-empted." *Id.* at 1006 (citing *Cupek*, 405 F.3d at 424) (international quotation marks omitted).

Last, Ms. Arnold's failure-to-warn claim differs from the state law failure-to-warn claims that this Court determined were not impliedly preempted under *Buckman* as part of the multidistrict litigation regarding hernia mesh devices. *See In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 2:18-CV-01509, 2020 WL 6603657, at *9–10 (S.D. Ohio Oct. 20, 2020). There, the Court explained that the hernia mesh device in question entered the market through the FDA's "510(k)" clearance process, which is distinct from and less rigorous than the FDA's pre-market approval process. *See In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 2:18-CV-01509, 2020 WL 5223363, at *1, 24–25 (S.D. Ohio Sept. 1, 2020). Accordingly, the express and implied preemption principles described above regarding FDA-approved medical devices, like Filshie Clips, were not applicable to the hernia mesh device, which was cleared through an equivalence process that did not involve an assessment

of the device's safety. *See id.* at *25 ("Whereas, if a device enters the market through the 510(k) process, the FDA has not evaluated the device for safety, and the device has no approval from the FDA in that regard." (quoting *Burningham v. Wright Med. Tech., Inc.*, 448 P.3d 1283, 1290 (Utah 2019))).

The Court's conclusion that Ms. Arnold's failure-to-warn claim based on a failure-to-report-adverse-events theory of liability is preempted by federal law aligns with decisions of other courts who have considered similar arguments about Filshie Clips. *See, e.g.*, *Mack v. CooperSurgical, Inc.*, No. 1:22-CV-54-RAH, 2024 WL 4427846, at *8 (M.D. Ala. Oct. 4, 2024) (Huffaker, J.) (granting summary judgment to the defendants on plaintiff's failure-to-warn claim); *Farson v. Coopersurgical, Inc.*, No. 3:22 CV 716, 2023 WL 5002818, at *11 (N.D. Ohio Aug. 4, 2023) (Knepp, J.) (granting motions to dismiss similar claims as preempted); *Froman v. Coopersurgical, Inc.*, No. 2:22-CV-00110-AKK, 2022 WL 2657117, at *6 (N.D. Ala. July 8, 2022) (Kallon, J.) (holding similar claims preempted); *Watters v. CooperSurgical, Inc.*, 655 F. Supp. 3d 376, 386 (E.D.N.C. 2023) (Dever, J.) (holding similar claims preempted). Ms. Arnold has not presented a unique argument to this Court that undermines the sound logic and reasoning of these decisions by other federal courts.

Because Ms. Arnold's failure-to-warn claim is preempted under federal law, no genuine issue of material fact remains as to Defendants' liability under state law. Accordingly, CooperSurgical and UTMP are entitled to summary judgment regarding Ms. Arnold's failure-to-warn claim.

CONCLUSION

The Court **GRANTS** CooperSurgical's Motion for Summary Judgment (ECF No. 115) and **GRANTS** UTMP's Motion for Summary Judgment (ECF No. 116). Femcare's Motion for

Summary Judgment is **DENIED AS MOOT**. (ECF No. 114.) Ms. Arnold's Motion for Summary Judgment is **DENIED**. (ECF No. 109.)

Because the Court concludes that Ms. Arnold's claim is preempted without relying on the disputed opinions of the Parties' expert witnesses, the Parties' motions to exclude various expert opinions are **DENIED AS MOOT**. (ECF Nos. 110, 111, 112, 117, 118, 119, 120.) And because no trial will occur, Ms. Arnold's Motion to Use Proposed Juror Questionnaire at Trial is also **DENIED AS MOOT**. (ECF No. 113.)

The Clerk is **DIRECTED** to enter judgment and to close this case on the Court's docket.

IT IS SO ORDERED.

2/26/2025
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE